

DMB

Display Date	2-28-00
Publication Date	2-29-00
Certifier	J. M. Lindner

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for 13 new animal drug applications (NADA's) from I. D. Russell Co., Laboratories to AlphaPharma Inc.

DATES: This rule is effective [*insert date publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: I. D. Russell Co., Laboratories, 1301 Iowa Ave., Longmont, CO 80501, has informed FDA that it has transferred the ownership of, and all rights and interest in, the following approved NADA's to AlphaPharma Inc., One Executive Dr., Fort Lee, NJ 07024:

NADA No.	Product Name
6-019	Zuco Poultry Tabs
6-081	Korum
6-776	10% Sulfaquinoxaline
6-860	Ruco Tablets
6-891	Liquid Sul-Q-Nox
8-902	Hepasol
100-094	Poultry Sulfa
100-175	20% Sulfaquinoxaline
100-176	34% Sulfaquinoxaline
130-435	Oxytet Soluble
200-106	R-Pen
200-189	Lincomycin Soluble
200-274	Lincomycin Injectable 30%

The agency is amending parts 510 and 520 (21 CFR parts 510 and 520) to reflect the change of sponsor. The agency is amending § 510.600(c)(1) and (c)(2) to remove the sponsor name for I. D. Russell Co., Laboratories because the firm no longer is the holder of any approved NADA's.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to congressional review requirements in 5 U.S.C 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 520 are amended as follows:

PART 510 NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 *Names, addresses, and drug labeler codes* of sponsors of approved applications is amended in the table in paragraphs (c)(1) by removing the entry for "I. D. Russell Co., Laboratories" and in the table in paragraph (c)(2) by removing the entry for "017144".

PART 520 ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.126³~~c~~ [Amended]

4. Section 520.1263c *Lincomycin hydrochloride soluble powder* is amended in paragraph (b) by removing “017144” and adding in its place “046573”.

§ 520.1660d [Amended]

5. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraphs (b)(2), (d)(i)(A)(3), (d)(i)(B)(3), (d)(i)(C)(3), and (d)(ii)(C) by removing “017144” and adding ⁰⁴⁶⁵⁷³ in its place “046573”. _{OFK}

§ 520.1696b [Amended]

6. Section 520.1696b *Penicillin G potassium in drinking water* is amended in paragraph (b) _{OFK} by removing “017144,”.

§ 520.2088 [Amended]

7. Section 520.2088 *Roxarsone tablets* is amended in paragraph (c)(2) by removing “017144” _{OFK} and adding in its place “046573”.

§ 520.2089 [Amended]

8. Section 520.2089 *Roxarsone liquid* is amended in paragraph (b) by removing “017144” _{OFK} and adding in its place “046573”.

§ 520.2325a [Amended]

9. Section 520.2325a *Sulfaquinoxaline drinking water* is amended in paragraph (a)(5) by removing "017144" and adding in its place "046573".

FR

Dated: 2/16/00
February 16, 2000

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jen Windsor

Claire M. Lathers

Claire M. Lathers
Director
Office of New Animal Drug
Evaluation
Center for Veterinary
Medicine

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F